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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,435	01/22/2004	Pablo Umana	1975.0180003/TJS	3728

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
GEBREYESUS, KAGNEW H	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,435	UMANA ET AL.	
	Examiner	Art Unit	
	Kagnew H. Gebreyesus	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-286* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-286* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, 28, 29, 35-64, 119-122, 126, 127, 130-185, 285 are drawn to an isolated nucleic acid, vectors and method of expression comprising a sequence encoding a fusion polypeptide, wherein said fusion polypeptide has β (1,4)-N-acetylglucosaminyltransferase III activity or β (1,4)-galactosyl transferase activity and comprises the Golgi localization domain of a Golgi resident polypeptide, classified in class 435, subclass 193.

II. Claims 21-27, 123-125, 286 are drawn to a fusion polypeptide having β (1,4)-N-acetylglucosaminyltransferase III activity or β (1,4)-galactosyltransferase activity and comprising the Golgi localization domain of a heterologous Golgi resident polypeptide, classified in class 435, subclass 193.

III. Claims 30-34 and 65-95, 128, 129, 186-212, 216-260 are drawn to a method for modifying the glycosylation profile of a polypeptide produced by a host cell, comprising introducing into said host cell the nucleic acid comprising a sequence encoding a fusion polypeptide, wherein said fusion polypeptide has β (1,4)-N-acetylglucosaminyltransferase III activity or β (1,4)-galactosyltransferase activity classified in class 435, subclass 455.

IV. Claims 96-114, 213, 214, 261-279 are drawn to an antibody engineered to have increased effector function produced by the method comprising introducing into said

host cell the nucleic acid comprising a sequence encoding a fusion polypeptide, wherein said fusion polypeptide has β (1,4)-N-acetylglucosaminyltransferase III activity or β (1,4)-galactosyltransferase activity classified in class 435, subclass 188.

V. Claims 115-118, 215, 280-284 are drawn to a method for the treatment of disease such as cancer comprising administering a therapeutically effective amount of a pharmaceutical composition comprising an antibody engineered to have increased effector function produced by the method comprising introducing the nucleic acid comprising a sequence encoding a fusion polypeptide, wherein said fusion polypeptide has β (1,4)-N-acetylglucosaminyltransferase III activity or β (1,4)-galactosyltransferase activity into a host cell classified in class 424, subclass 130.1.

The DNA of Group I and the protein of Group II each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA comprises a nucleic acid sequence and the protein of group II comprise unrelated amino acid sequences. The DNA has other utilities besides encoding the protein such as hybridization probe, the proteins can be made by another method such as isolation from natural sources or chemical synthesis.

The DNA of Group I and the antibody of group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as being capable of use together and they have different modes of operation, different function, or different effects (MPEP 806.04, MPEP 808.01). In the

instant case the DNA in group I are separate and distinct from the antibodies in group IV as they are physically and functionally distinct chemical entities. Accordingly restriction is appropriate.

2. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the glycosylation profile of a polypeptide can be modified using vectors comprising genes encoding other glycosyltransferases.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions group I is drawn to nucleic acid sequences and Group V is drawn to a method of treating a disease which does not require the polynucleotide cannot be used together with the antibody in the treatment method.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, group II is drawn to polypeptide sequence and Group III drawn to a method of modifying the glycosylation profile of a polypeptide using a vector comprising a polynucleotide sequence thus the fusion polypeptide is not used in host cell.

Inventions in group II are unrelated to group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polypeptides. Therefore, where structural identity is required, such as for production of antibodies using polypeptides, the different sequences have different effects.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, group II is drawn to polypeptide sequence not used in the method of treatment of disease.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make glycosylated products other than the modified antibody of invention IV.

The inventions of Groups III and V are independent as they comprise different steps, utilize different products and/or yield different results. In addition the search and examination of each method in Groups III and V in one patent application would result in undue burden, since the searches for all the groups are not co-extensive, since the searches are in different classifications, and involve different field of search. Each of the of the inventions requires a separate patent and non-patent literature search requiring a different text search for each group

and thus co examination of the inventions in groups III and V would be a serious burden on the examiner.

3. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case other compounds can be used in a method of treatment that do not require the antibody can be used.

1. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43).

3. Applicant is reminded that upon the cancellation of claims to a none elected invention the none elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of

the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

5. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagnew Gebreyesus Ph.D.
AU 1652

REBECCA E. PRUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600